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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/731,316	12/06/2000	Carlos Schuler	015225-005210US	1043

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NEKTAR THERAPEUTICS
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EXAMINER

MENDOZA, MICHAEL G

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 01/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/731,316

Applicant(s)

SCHULER ET AL.

Examiner

Michael G. Mendoza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 and 52-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 52-60 is/are allowed.
- 6) ☒ Claim(s) 1-18, 21, 23-29, 35-39, 43-49, 61 and 62 is/are rejected.
- 7) ☒ Claim(s) 19, 20, 22, 30-36, 40-42, 50 and 63 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f):
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 30 December 2004 have been fully considered but they are not persuasive. The Applicant argues that Smith et al. does not teach providing at least one pulse of energy to a receptacle to increase the efficiency at which the powder may be extracted. Energy is defined as the capacity for doing work. In Smith the high velocity air works on agglomerates of particles prior to being dispersed. The high velocity air provides energy to break up agglomerates. The Applicant also argues that McGinn et al. fails to teach providing a pulse of energy to increase aerolization efficiency and flowing a gas through a chamber to aerosolize the powder. In McGinn a snap action pulse releases an powder medicament into a cloud of particle more suitable for aerosolization. The cloud is carried through a chamber by air provided by a fan aerosolizing the medicament (pg. 24, lines 8-24). The motivation to combine Smith with McGinn is to fully release/deaggregate medicament prior to delivery. The Applicant also argues that Abrams et al. fails to teach flowing a gas through a chamber to aerosolize the powder. In one embodiment Abrams teaches vibrating a medicament then suspending the deaggrated medicament in an air stream (col. 4, lines 25-40). Abrams does teach a pulse of energy and flow a gas to aerosolize. Never-the-less, Smith teaches aerosolizing a deaggrated medicament by flow of air and deaggrating a medicament. Abrams teaches an alternative means for deaggrating the medicament.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3-7, 11, 15, 16, 18, 21, 25-29, 38, 39, 45-49, 61 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. 5740794 in view of McGinn et al. WO 99/44663.

4. Smith et al. teaches a method for conditioning a packaged powder, the method comprising: providing a receptacle 12 having an enclosed chamber containing an amount of a powder; and flowing a gas through the chamber to aerosolize the powder (col. 13, lines 22-35). Smith et al. fails to teach providing at least one pulse of energy to the receptacle.

McGinn et al. teaches a method using a common pulse of energy to release medicament (pg. 24, lines 8-18). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the step of McGinn et al. to release/deaggregate medicament for delivery to the patient.

5. Smith/McGinn teaches a method and system for conditioning a packaged powder, the method further comprising: releasing a spring loaded lever (pg. 27, lines 12-19); bending the device and then quickly releasing the receptacle (pg. 22, line 24-25 and pg. 23, lines 1-7); moving the receptacle past an area that temporarily engages a portion of the receptacle (pg. 22, line 24-25 and pg. 23, lines 1-7); wherein the powder

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is composed of fine particles having a mean size in the range from 0.5 micrometer to about 5 micrometers (pg. 5, lines 14-15); wherein the receptacle further comprises a metallic body having a tube extending from the chamber (pg. 16, lines 12-15); a container having an enclosure, and wherein the mechanism is coupled to the container, wherein the container comprises a base and a cover that is pivotally coupled to the base (figs. 1 and 2); a coupling arrangement that couples the receptacle to the base (fig. 2); an aerosolization system comprising a mouthpiece 72.

6. As to claim 4, Smith/McGinn teaches the method as in claim 3. It should be noted fails to specifically teach striking the receptacle with an amount of energy of at least about 0.01 lbf-in. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to strike the receptacle at a force strong enough to provide sufficient energy to deaggregate the powder. The limitations as claimed can be obtained through routine observation and experimentation. Furthermore, the Applicant has not disclosed why the particulars of limitations are of importance or solve a stated problem or provide an advantage over the prior art.

7. As to claim 46-48, Smith/McGinn teaches a kit for aerosolizing a powder, comprising: at least one receptacle having an enclosed chamber; and an aerosolization device having an opening. It should be noted that McGinn et al. does not specifically teach instructions. However, it would have been inherent to include instructions for proper use of the kit to insure optimum results.

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8. As to claim 49, Smith/McGinn teaches a kit as in claim 48, wherein the powder conditioning device comprises a frame and a spring-loaded lever are pivotally coupled to the frame, wherein the lever are is releasable to strike the receptacle.

9. As to claim 62, Smith/McGinn fails to teach wherein the pulse of energy is provided within about 100 ms before actuation of the aerosolization system to about 23 ms after the actuation of the aerosolization system. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made provide the pulse of energy during the range set forth in the claim to insure complete inhalation of the medication. The limitations as claimed can be obtained through routine observation and experimentation. Furthermore, the Applicant has not disclosed why the particulars of limitations are of importance or solve a stated problem or provide an advantage over the prior art.

10. Claim 2 rejected under 35 U.S.C. 103(a) as being unpatentable over Smith/McGinn in further view of Gonda et al. 6167880.

11. As to claim 2, Smith/McGinn teaches the method as in claim 1. It should be noted that Smith/McGinn fails to teach providing the pulse of energy while the powder is sealed within the chamber.

Gonda teaches a common method of providing a pulse of energy in a sealed chamber to deaggregate/aerosolize the powder before inhalation. Therefore it would have been obvious to one of ordinary skill in the art to modify the method of Smith/McGinn to include the method step of Gonda et al. to deaggregate/aerosolize the powder before inhalation (col. 41, lines 59-62).

12. Claim 12 rejected under 35 U.S.C. 103(a) as being unpatentable over Smith/McGinn in further view of Abrams et al.

13. As to claim 12, Smith/McGinn teaches the method as in claim 1. It should be noted that Smith/McGinn fails to teach providing at least one pre-conditioning step prior to providing the at least one pulse of energy, wherein the pre-conditioning step comprises vibrating the receptacle for a predetermined period of time.

Smith/Abrams teaches a common method of pre-conditioning to provide only deaggregated drug particle are used. Therefore, it would have been obvious to one of ordinary skill in the art to modify the method of Smith/McGinn to include the method step of Abrams et al. to obtain only smaller sized deaggregated particles (col. 6, lines 18-19).

14. Claims 1, 8-11, 13-15, 23, 24, 26, 27, 37, 43-45, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. in view of Abrams et al. 5694920.

15. Smith et al. teaches a method for conditioning a packaged powder, the method comprising: providing a receptacle 12 having an enclosed chamber containing an amount of a powder; and flowing a gas through the chamber to aerosolize the powder (col. 13, lines 22-35). Smith et al. fails to teach providing at least one pulse of energy to the receptacle.

Abrams et al. teaches a method using a common pulse of energy to deaggregate medicament (col. 7, lines 42-44). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the step of Abrams et al. to release/deaggregate medicament for delivery to the patient.

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16. Smith/Abrams teaches a method and system for conditioning a packaged powder, the method and system further comprising: providing at least one pulse of energy comprising providing a pulse of vibratory energy (col. 7, lines 42-44); contacting the receptacle with a vibrating piezoelectric transducer (col. 7, lines 42-44); wherein the powder is composed of fine particle having a mean size in the range from about 0.5 micrometers to about 5 micrometers (col. 1, lines 40-43); an aerosolization system comprising a mouthpiece 218.

17. As to claims 10 and 13, Smith/Abrams teaches the method as in claim 9. It should be noted that Smith/Abrams fails to teach vibrating the transducer at a frequency of at least about 10 kHz. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to vibrate the transducer at a frequency high enough to provide sufficient energy to deaggregate and/or aerosolize the powder to sufficient size to be inhaled by the user. The limitations as claimed can be obtained through routine observation and experimentation. Furthermore, the Applicant has not disclosed why the particulars of limitations are of importance or solve a stated problem or provide an advantage over the prior art.

18. As to claim 14, Smith/Abrams teaches the method as in claim 1. It should be noted that Smith/Abrams fails to teach wherein the receptacle is vibrated for about 0.01 minute to about 10 minutes.. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to vibrate the receptacle for an amount of time long enough to deaggregate the powder. The limitations as claimed can be obtained through routine observation and experimentation. Furthermore, the

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Applicant has not disclosed why the particulars of limitations are of importance or solve a stated problem or provide an advantage over the prior art.

Allowable Subject Matter

19. Claims 19, 20, 22, 30-36, 40-42, 50 and 63 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

20. Claims 52-60 are allowable over the prior art of record.

21. The following is a statement of reasons for the indication of allowable subject matter: the prior art of record fails to teach or render obvious the overall claimed invention of a mechanism comprising a hook coupled to a cover this is adapted to engage and then release the receptacle when the cover is pivoted to permit the receptacle to strike a base, or

a coupling arrangement is pivotally coupled to a base, and wherein a mechanism comprises a latch that is operably coupled to a base, an arm that is coupled to a cover, and a cantilever beam that is attached to the coupling arrangement, wherein the arm is configured to engage and pivot the coupling arrangement as the cover is opened, and wherein the latch is configured to engage and then release the cantilever beam when the coupling arrangement is pivoted to permit the cantilever beam to strike the receptacle, or

a mechanism comprising a spring that is coupled a cover and a latch that is operably coupled to the base, wherein the latch is operable to release the spring to permit the spring to strike the receptacle, or

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a container is adapted to hold a plurality of stacked receptacles, and wherein a mechanism comprises a biased striking member and a trigger that is movable between a home position and a striking position, wherein the movement of the trigger to the striking position releases the striking member to permit the striking member to strike one of the receptacles.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Glenn Dawson can be reached on (571) 272-4694. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MM


GLENN K. DAWSON
PRIMARY EXAMINER